

REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart K: Other Medical Uses of Byproduct or Radiation from Byproduct Material

New Subpart K includes all new medical uses of byproduct material or radiation from byproduct material, i.e., types of uses that are not regulated under Subparts D through H

- Revised and moved old §35.990, Violations, to new §35.4001
- Revised and moved §35.991, Criminal penalties, to new §35.4002
- Revised and moved old §35.999, Resolution of conflicting requirements during transition period, to new § 35.10

§35.1000 Other medical uses of byproduct material or radiation from byproduct material

- Note: This new section provides a more clearly defined process to obtain a license, or an amendment to a license, for a new medical use (i.e., emerging technology). The specific information that must be provided to NRC in support of such an application is provided in new §35.12(d).
 - ▶ NRC intends to evaluate each application on a case-by-case basis and to work with the ACMUI, the medical community, and the developers of the new technology, as appropriate, to determine the risks associated with the technology and the appropriate regulatory requirements, including the training and experience requirements, for use of the technology.